Sienco, Inc.
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Wheat Ridge, CO 80033 USA
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800/432-1624

AUG 31 2000

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002528 .

(1) **Contact Person:** Barbara DeBiase, Director, Sienco Inc.
Summary Preparation Date: 10 August 2000

(2) **Device Trade Name:** Sonoclot® Coagulation & Platelet Function Analyzer System with Signature Viewer™ Option
Common Name: Coagulation Analyzer
Classification Name: Multipurpose System for in vitro coagulation studies
Classification: Class II, 21 CFR 864.5425

(3) **Identification of predicate device to which substantial equivalence is being claimed:** Sonoclot Coagulation & Platelet Function Analyzer, 510(k) # K952560

(4) **and (5) Device Description and Intended Use:** The Sonoclot Coagulation & Platelet Function Analyzer System is an in vitro diagnostic device for measuring coagulation and platelet function. This system has two configurations. The standard configuration is a Sonoclot Analyzer connected to a thermal graphics printer. This 510(k) provides for a second optional configuration whereby the Sonoclot Analyzer is connected to a computer instead of the thermal graphics printer and displays results using Sienco's new Signature Viewer Data Collection Program. Signature Viewer includes an additional numerical output generated from the Sonoclot Signature called Platelet Function.

The Sonoclot Analyzer is a reliable and simple to use instrument which has been utilized in operating rooms, coagulation labs, STAT labs and intensive care units since 1974. The Sonoclot Analyzer System rapidly provides information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis.

The Sonoclot Analyzer System generates a qualitative graph, known as the Sonoclot Signature, and quantitative results on the clot formation time (Activated Clotting Time - Onset), the rate of fibrin polymerization (Clot Rate), and clot retraction (Platelet Function). This information can be used to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis. Different disposable tests are available for use with the Sonoclot Analyzer System for different applications.

(6) SONOCLOT ANALYZER SYSTEM CONFIGURATION COMPARISON

ITEM	SIGNATURE VIEWER CONFIGURATION	STANDARD CONFIGURATION
Classification Name	Multipurpose system for in vitro coagulation studies	Multipurpose system for in vitro coagulation studies
System Components	Sonoclot Analyzer(s) Signature Viewer CD User provided personal computer	Sonoclot Analyzer Thermal Graphics Printer
Intended Use	Provides rapid information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis	Provides rapid information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis
Results Provided	Quantitative results for Activated Clotting Time (Sonoclot Onset Time) and rate of fibrin polymerization (Sonoclot Clot Rate). Qualitative and quantitative platelet function information (time to peak, platelet function, and clot retraction).	Quantitative results for Activated Clotting Time (Sonoclot Onset Time) and rate of fibrin polymerization (Sonoclot Clot Rate). Qualitative and quantitative platelet function information (time to peak, clot retraction).

(7) OUTPUT COMPARISON

Sonoclot Analyzer outputs from Signature Viewer and the Thermal Graphics Printer are provided on the following pages. Both outputs include Quantitative ACT and Clot Rate results. Both outputs also include the Sonoclot Signature which contains qualitative and quantitative platelet function information. Signature Viewer includes an additional numerical output generated from the Sonoclot Signature called Platelet Function. The Platelet Function result is intended for reference purposes only.

Jon Henderson

Jon Henderson, President

Thermal Graphics Printer Output

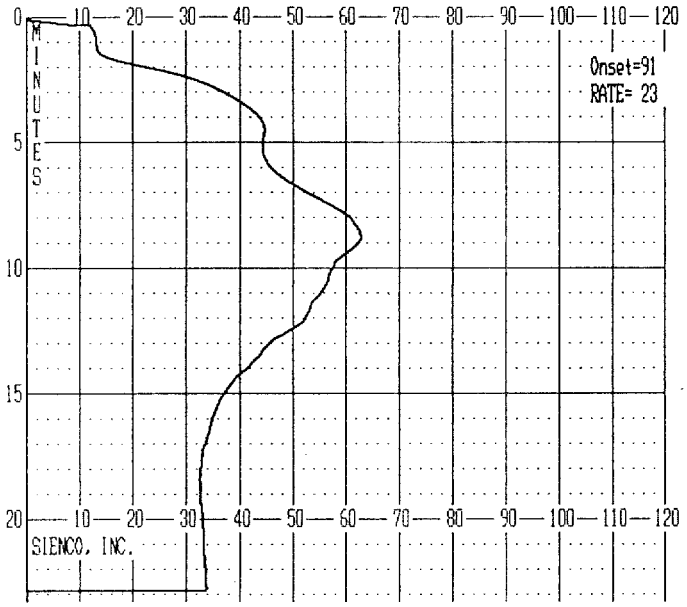
Patient: K3 Normal

Date: 6-29-98 Time: _____

Comments: _____

SIENCO Sonoclot(R) Coagulation and Platelet Function Analyzer
Firmware Version 3.1.6 Copyright 1992-1996 Serial Number 2029 Board Rev 3.6
Scale: 0-120 Compressed Auto
Temperature Setpoint: 37.00
Automatic shutoff after 60 minutes

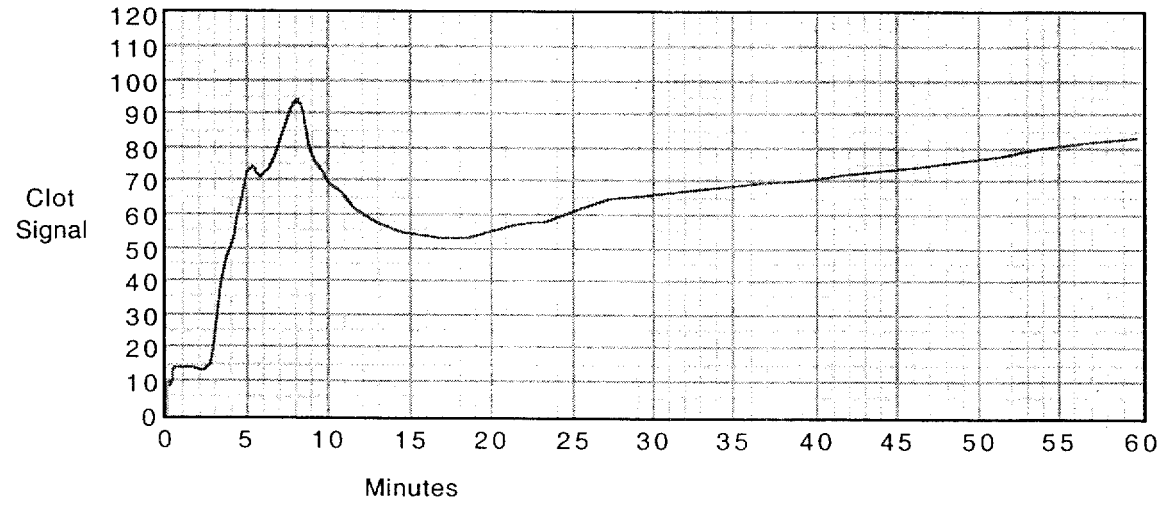
Clot Signal



Onset = 91
Clot RATE = 23

Signature Viewer Output

Baseline

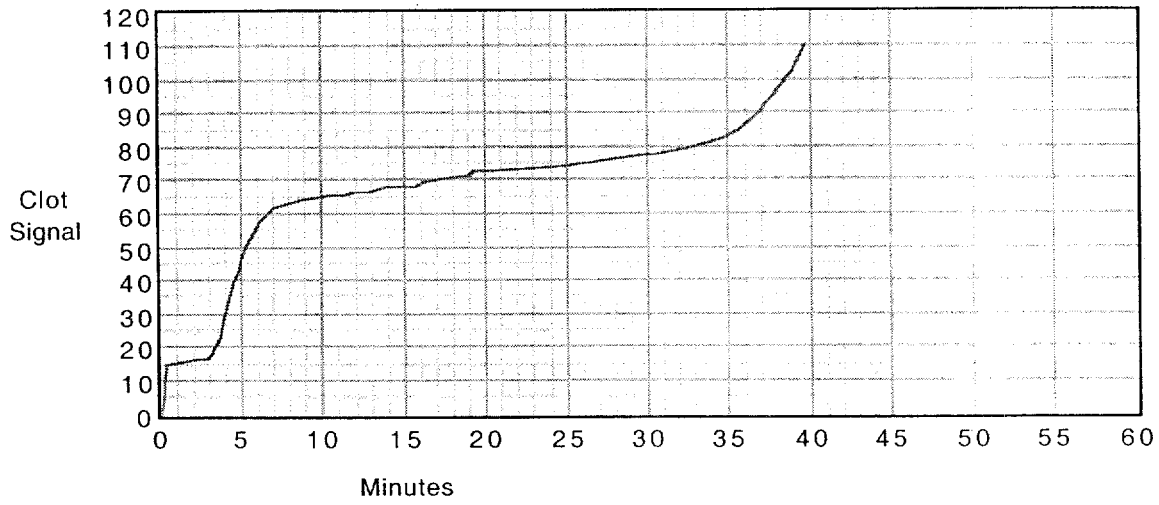


ACT/Onset: 161
Clot RATE: 40
Platelet Function: 4.8
Serial Number: ?
Collection Date: 1999.01.24, 22:06
Filename: Library/Reopro Examples/Signature 1
Type of Cuvette: gbACT+
Patient ID:
Application:
Description:

Print Date: 2000.06.27, 12:41

Signature Viewer Output

Recommened Dose of ReoPro



ACT/Onset: 186
Clot RATE: 18
Platelet Function: 0.9
Serial Number: ?
Collection Date: 1999.01.24, 22:07
Filename: Library/Reopro Examples/Signature 2
Type of Cuvette: gbACT+
Patient ID:
Application:
Description:

Print Date: 2000.06.27, 12:48

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Barbara DeBiase
Director
Sienco, Inc.
11485-A West 48th Avenue
Wheat Ridge, Colorado 80033

AUG 31 2000

Re: K002528
Trade Name: Sonoclot® Coagulation & Platelet Function Analyzer System with Signature Viewer™ Option
Regulatory Class: II
Product Code: JBP
Dated: August 10, 2000
Received: August 16, 2000

Dear Ms. DeBiase:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002536

Device Name:_____

_____

Indications For Use:

The Sonoclot Coagulation & Platelet Function Analyzer System is an in vitro diagnostic device for measuring coagulation and platelet function. This system has two configurations. The standard configuration is a Sonoclot Analyzer connected to a thermal graphics printer. This 510(k) provides for a second optional configuration whereby the Sonoclot Analyzer is connected to a computer instead of the thermal graphics printer and displays results using Sienco's new Signature Viewer Data Collection Program. Signature Viewer includes an additional numerical output generated from the Sonoclot Signature called Platelet Function.

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The Sonoclot Analyzer System generates a qualitative graph, known as the Sonoclot Signature, and quantitative results on the clot formation time (Activated Clotting Time - Onset), the rate of fibrin polymerization (Clot Rate), and clot retraction (Platelet Function). This information can be used to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis. Different disposable tests are available for use with the Sonoclot Analyzer System for different applications.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002536

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)